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|---|--|---|
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | ATTORNEY'S DOCKET NUMBER<br>2294-0119PUS1<br>U. S. APPLICATION NO. (if known; see 37 CFR 1.5)<br><b>107589377</b> |
| INTERNATIONAL APPLICATION NO.<br>PCT/EP2005/001038  | INTERNATIONAL FILING DATE<br>2 February 2005 | PRIORITY DATE CLAIMED<br>3 February 2004  |
| TITLE OF INVENTION<br><b>HYPOCHOLESTEROLEMIC COMPOSITIONS COMPRISING A STATIN AND AN ANTIFLATULENT AGENT</b>  |  |   |
| APPLICANT(S) FOR DO/EO/US<br><b>Marta GUERRERO, Anna ORRIOLS, Manuel M. RAGA and Antonio GUGLIETTA</b>  |  |   |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |   |
| <p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> |  |   |

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| U. S. PATENT AND TRADEMARK OFFICE; 37 CFR 1.5<br>NEW   |              | INTERNATIONAL APPLICATION NO.<br>PCT/EP2005/001038                               | ATTORNEY'S DOCKET NUMBER<br>2294-0119PUS1 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
|--|--------------|--|---|-------------|--------|--------------|--------------|------|--|--------------|-----------|----|---|-------|--------------------|---------|--|---|--|---|--|--|---|--------|--|--|--|--|--|
| 20. <input checked="" type="checkbox"/> Other items or information: Return Receipt Postcard<br>Drawings (1 sheet)<br>PCT/ISA/210, PCT/IB/301, PCT/IB/304, PCT/IB/308, PCT/IB/409<br>Letter Submitting Article 19-34 Amendments   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| The following fees have been submitted   |              |  | CALCULATIONS                              | PTO USEONLY |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300   |              |  | \$ 300.00                                 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))<br>If the written opinion prepared by ISA/US or the international preliminary examination report<br>prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). ..... \$0<br>All other situations ..... \$200  |              |  | \$ 200.00                                 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))<br>If the written opinion of the ISA/US or the international preliminary examination report prepared by<br>IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). ..... \$0<br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an<br>International Searching Authority ..... \$100<br>International Search Report prepared by an ISA other than the US and provided to the Office or<br>previously communicated to the US by the IB ..... \$400<br>All other situations ..... \$500 |              |  | \$ 400.00                                 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| TOTAL OF 21, 22 and 23 =   |              |  | \$ 900.00                                 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding<br>sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an<br>electronic medium) (37 CFR 1.492(j)).<br>The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Total Sheets   | Extra Sheets | Number of each additional 50 or fraction<br>thereof (round up to a whole number) | RATE                                      |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| 22 - 100 =   | /50 =        |  | x \$250.00                                |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration<br>after the date of commencement of the national stage (37 CFR 1.492(h)).  |              |  | \$ 130.00                                 |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| <table border="1"> <thead> <tr> <th>CLAIMS</th> <th>NUMBER FILED</th> <th>NUMBER EXTRA</th> <th colspan="2">RATE</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>32 - 20 =</td> <td>12</td> <td>x</td> <td>50.00</td> </tr> <tr> <td>Independent claims</td> <td>1 - 3 =</td> <td></td> <td>x</td> <td></td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+</td> <td>360.00</td> </tr> <tr> <td colspan="5">TOTAL OF ABOVE CALCULATIONS = \$ 1990.00</td> </tr> </tbody> </table>  |              |  |   |             | CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE |  | Total claims | 32 - 20 = | 12 | x | 50.00 | Independent claims | 1 - 3 = |  | x |  | MULTIPLE DEPENDENT CLAIM(S) (if applicable) |  |  | + | 360.00 | TOTAL OF ABOVE CALCULATIONS = \$ 1990.00 |  |  |  |  |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA   | RATE                                      |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Total claims   | 32 - 20 =    | 12   | x   | 50.00       |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Independent claims   | 1 - 3 =      |  | x   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |  | +   | 360.00      |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| TOTAL OF ABOVE CALCULATIONS = \$ 1990.00   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| SUBTOTAL = \$ 1990.00  |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest<br>claimed priority date (37 CFR 1.492(i)).   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| TOTAL NATIONAL FEE = \$ 1990.00  |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied<br>by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| \$   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
| TOTAL FEES ENCLOSED = \$ 1990.00   |              |  |   |             |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
|  |              |  | Amount to be<br>refunded:                 | \$          |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |
|  |              |  | Amount to be<br>charged                   | \$          |        |              |              |      |  |              |           |    |   |       |                    |         |  |   |  |   |  |  |   |        |  |  |  |  |  |

10/588377

IAP11 Rec'd PCT/PTO 02 AUG 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 03/31/2007. OMB 0651-0021

U. S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

a.  A check in the amount of \$ 1990.00 to cover the above fees is enclosed.

b.  Please charge my Deposit Account No. 02-2448 in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448. A duplicate copy of this sheet is enclosed.

d.  Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Marc S. Weiner  
SIGNATURE

August 2, 2006

Marc S. Weiner  
NAME

CUSTOMER NUMBER: 02292

32,181  
REGISTRATION NUMBER

/sns

10/588377

IAP11 Rec'd PCT/PTO 02 AUG 2006

Docket No.: 2294-0119PUS1  
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of:  
Marta GUERRERO et al.

Application No.: NEW

Confirmation No.: N/A

Filed: August 2, 2006

Art Unit: N/A

For: HYPOCHOLESTEROLEMIC COMPOSITIONS  
COMPRISING A STATIN AND AN  
ANTIFLATULENT AGENT

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Examiner: Not Yet Assigned

LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto to the International Preliminary Examination Report during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Dated: August 2, 2006

Respectfully submitted,

By Marc S. Weiner  
Marc S. Weiner

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Attachment(s)